

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION**

JULIA SHONKWILER, Individually and as
Parent and Natural Guardian of B.C.W., a Minor

Plaintiff,

vs.

GLAXOSMITHKLINE, LLC.

Defendant.

CIVIL ACTION NO. 5:15-cv-00034

**DEFENDANT GLAXOSMITHKLINE LLC'S MOTION TO DISMISS
PLAINTIFF'S COMPLAINT FOR FAILURE TO STATE A CLAIM
AND MEMORANDUM IN SUPPORT**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant GlaxoSmithKline LLC ("GSK") respectfully moves to dismiss Plaintiff's Second, Fourth, Fifth, Sixth, Seventh, and Tenth Causes of Action for failure to state a claim upon which relief can be granted. The Court should also dismiss Plaintiff's Eighth Cause of Action, to the extent it is based on an implied warranty of fitness for a particular purpose. In support of its motion, GSK states as follows:

I. INTRODUCTION

This product liability action concerns Zofran®, a prescription medication approved by the Federal Food and Drug Administration ("FDA") for the treatment of nausea. Zofran® has been prescribed by physicians for over two decades. Plaintiff Julia Shonkwiler alleges that she ingested Zofran® while she was pregnant with B.C.W. and that her ingestion of Zofran caused B.C.W. to be born with congenital birth defects. (Compl. ¶¶ 207, 209.) On the basis of these allegations, Plaintiff asserts ten causes of action against GSK: (1) negligence, (2) negligence per se, (3) strict products liability, (4) fraudulent misrepresentation, (5) fraudulent concealment, (6)

negligent misrepresentation, (7) breach of express warranty, (8) breach of implied warranty of merchantability and fitness for a particular use, (9) deceptive trade practices and Consumer Protection Act violations, and (10) loss of consortium. (*Id.* ¶¶ 217-308.) Seven of these causes of actions are factually lacking and are otherwise legally deficient. Accordingly, they must be dismissed for failure to state a claim.

In Count 2 of her Complaint, Plaintiff asserts a cause of action for negligence per se, but the claim is based on statutes and regulations for which she cannot establish a viable theory of recovery under Texas law.

In Counts 4, 5, and 6, Plaintiff asserts causes of action for common law fraud, negligent misrepresentation and fraudulent concealment. However, the allegations in her Complaint fall well short of the requisite level of specificity required by Fed. R. Civ. P. Rule 9(a). Separately, Plaintiff's fraud-based claims fail as a matter of substance because she has not pleaded any facts establishing reliance.

In Counts 7 and 8, Plaintiff asserts causes of action for breach of express warranty and for breach of the implied warranty of fitness for a particular purpose. However, nowhere in her Complaint does Plaintiff allege any facts establishing that GSK made any express warranty to her. Nor does she allege any facts establishing the applicability of the implied warranty of fitness for a particular purpose.

Finally, in Count 10, Plaintiff asserts a cause of action for loss of consortium, which is not available to her under Texas jurisprudence.

For these reasons and those more fully set forth below, Plaintiff's Second, Fourth, Fifth, Sixth, Seventh, and Tenth Causes of Action should be dismissed. Plaintiff's Eighth Cause of

Action should be dismissed to the extent it is based on an implied warranty of fitness for a particular purpose.

II. FACTUAL BACKGROUND¹

GSK manufactures and has sold ondansetron under the brand name Zofran®. Zofran® (ondansetron) is an anti-emetic² medication belonging to the class of drugs known as selective serotonin 5-HT₃ receptor antagonists. (*See* Compl. ¶ 117.) The FDA approved Zofran® 24 years ago, in 1991, for the prevention of nausea and vomiting associated with emetogenic cancer chemotherapy and for the prevention of postoperative nausea or vomiting. (*See* FDA-Approved Package Insert for Zofran®, NDA 20-007, *available at*: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name; *see also* Compl. ¶ 9).

Plaintiff alleges that, in or about 2013 or 2014, her physician decided to prescribe her Zofran® “off label” for the treatment of morning sickness during her pregnancy with B.C.W. (Compl. ¶ 207.) Plaintiff further alleges that B.C.W. was born in 2014 and was diagnosed with “congenital heart and brain defects,” as well as “numerous other congenital defects,” none of which Plaintiff specifies. (Compl. ¶ 209.)

Although Zofran® was not indicated for the treatment of morning sickness, the FDA-approved label that was in effect when Plaintiff ingested the medication stated as follows:

¹ In light of the Court’s standard of reviewing the pleadings under Rule 12(b)(6), the following recitation of facts is based on the Plaintiff’s Complaint and the documents referred to in the Complaint, of which the Court may take judicial notice. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007) (standing for the proposition that, on a Rule 12(b)(6) motion, a court may consider “documents incorporated into the complaint by reference”). GSK expressly reserves the right to contest each and every allegation in any subsequent proceedings.

² “Emesis” is the medical term for nausea and vomiting, thus anti-emetics are products that treat nausea and vomiting. (Compl. ¶ 116.)

Pregnancy: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at intravenous doses up to 4 mg/kg per day (approximately 1.4 and 2.9 times the recommended human intravenous dose of 0.15 mg/kg given three times a day, respectively, based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. **Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.**

(See FDA-Approved Package Insert for Zofran®, NDA 20007, available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name.) (emphasis supplied).

Throughout her Complaint, Plaintiff asserts that GSK engaged in unlawful “off-label” promotion of Zofran®, based on a settlement GSK entered into with the Department of Justice (“DOJ”) in 2012 in connection with Zofran® and a number of other pharmaceutical products. As is clear from the settlement documents, however, DOJ’s allegations regarding GSK’s marketing of Zofran® was specifically limited to a time period between 2002 and 2004 – a *decade* before Plaintiff’s physician prescribed the medication to her. (Settlement Agreement, available at: <http://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-ex-b.pdf>.) Further, there were no findings that GSK ever illegally marketed Zofran® during this or any other period, and GSK never admitted wrongdoing with respect to Zofran®.

In her Complaint, Plaintiff also relies on a letter from FDA’s Division of Drug Marketing, Advertising and Communications (DDMAC) in March 1999. In that letter, DDMAC addressed certain GSK promotional materials pertaining to the use of Zofran® in connection with chemotherapy treatments. (See Compl. ¶ 200) (citing FDA Ltr. to Michele Hardy (Mar. 9, 1999), available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharma>

ceuticalCompanies/UCM166133.pdf). The letter had nothing to do with alleged “off label” promotion of Zofran® for morning sickness.

Finally, in support of her claim that GSK failed to convey accurate or complete information regarding the risks of birth defects associated with the use of Zofran® during pregnancy, Plaintiff principally relies on three observational studies, whose findings are varied and inconsistent. (Compl. ¶ 148.) Plaintiff also cites to a number of animal toxicology studies, (Compl. ¶ 131), however, she does not identify when those studies were performed, nor does she allege that any of those studies established that there was an increased risk for birth defects in humans as a result of the ingestion of Zofran® during pregnancy—much less that any of these studies established an increased risk for the specific birth defects diagnosed in B.C.W. *See id.*

III. LEGAL STANDARD

To survive dismissal under Rule (12)(b)(6), Rule 8 requires “more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Instead, a “complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Id.* at 678 (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. However, plausibility requires more than a mere “possibility that a defendant has acted unlawfully.” *Id.* Thus, for a complaint to survive a motion to dismiss, the “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555. A proper pleading “requires more than labels and conclusions,” *id.*, and “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* Similarly, “naked

assertions devoid of further factual enhancement” are also insufficient and must be disregarded. *Id.* (internal quotations marks and citation omitted).

With respect to Counts 2, 4, 5, 6, 7, 8, and 10, the allegations in Plaintiff’s Complaint fall well short of this threshold.

IV. ARGUMENT

A. Plaintiff’s Negligence Per Se Claim Fails as a Matter of Law

Plaintiff’s Second Cause of Action alleges that GSK violated a federal Food, Drug, and Cosmetic Act (“FDCA”) statute, an FDA regulation, and a healthcare anti-kickback statute, the violations of which amount to negligence per se. (Compl. ¶ 232) (citing 21 U.S.C. §§ 331, 352; 21 C.F.R. §§ 201.57, 201.128; and 42 U.S.C. § 1320a-7b). Negligence per se is a tort theory whereby courts use statutes or regulations to define the standard of reasonably prudent conduct. *See Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979). “Courts are not required to find negligence per se from a violation of a federal statute, particularly where the violation would not give rise to liability under state common law.” *Hacket v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (citing *Johnson v. Sawyer*, 47 F.3d 716, 728–29 (5th Cir.1995) (en banc)).

Because the FDCA does not provide for a private cause of action, Texas courts have found that “the FDCA and FDA regulations do not give rise to a negligence per se cause of action under the standard the Texas Supreme Court established in *Perry v. S.N.*, 973 S.W.2d 301 (Tex. 1998).” *Hacket*, 246 F. Supp. 2d at 594; *Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334, at *8 (Tex. Dist. June 7, 1999). Indeed, the U.S. Supreme Court has stated that the FDCA “leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance.” *Buckman Co. v. Plaintiffs’ Legal*

Comm., 531 U.S. 341, 349 n. 4 (2001); *see also* 21 U.S.C. § 336 (1994) (vesting complete discretionary authority over prosecuting statutory violations); *Pedimed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 723–24 (D. Md. 2006) (FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act); *Franzese v. St. Jude Med., Inc.*, No. 13–CV–3203(JS)(WDW), 2014 WL 2863087, *3 (E.D.N.Y. June 23, 2014) (“The FDA regulations themselves do not provide a private cause of action.”). Plaintiff’s negligence per se claim thus improperly attempts to enforce the FDCA and FDA regulations by means of a private suit. *Baker*, 1999 WL 811334, at *18; *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) (“Because [FDA] decisions are frequently of a discretionary nature [and] frequently require expertise, the agency should be given the first chance to exercise that discretion . . . [Plaintiff’s] position would require us to usurp [the FDA’s responsibility] for interpreting and enforcing potentially ambiguous regulation.”)

Texas law provides that “a statute or regulation can be adopted as a standard of negligence per se only when it adequately encapsulates the standard imposed by a preexisting, independent state law duty.” *Baker*, 1999 WL 811334, at *18. Because the statutes and regulations Plaintiff cites “do not adequately correspond to Texas products liability torts,” *id.*, and because Texas courts have expressly held FDCA and FDA regulations cannot form the basis of negligence per se, Plaintiff’s claim fails as a matter of law.

B. Plaintiff’s Claims for Breach of Express Warranty and Breach of Implied Warranty for Fitness for a Particular Purpose Must Be Dismissed

In her Seventh and Eighth Causes of Action, Plaintiff attempts to recast her failure-to-warn theory as claims for breach of express and breach of the implied warranty of fitness for a particular purpose. Neither of these claims is viable and both must be dismissed.

First, Plaintiff fails to allege the existence of any express warranty. An express warranty is created by an “affirmation of fact or promise made by the seller to the buyer,” a “description of the goods,” or a “sample or model” that becomes part of the “basis of the bargain.” TEX. BUS. & COM. CODE ANN. § 2.313. Plaintiff’s Complaint merely alleges as follows:

Defendants [sic] expressly warranted that:

- a. Zofran was safe and effective for treating pregnancy-related nausea;
- b. Zofran had been adequately tested and studied in pregnant women;
- c. Zofran’s use during pregnancy did not increase the risk of bearing children with birth defects; and
- d. Zofran’s “Pregnancy Category B” designation established the safety and efficacy of Zofran for treating pregnancy-related nausea.

(Compl. ¶ 281.) As discussed above, the Zofran® label stated as follows:

Pregnancy: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at intravenous doses up to 4 mg/kg per day (approximately 1.4 and 2.9 times the recommended human intravenous dose of 0.15 mg/kg given three times a day, respectively, based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. **Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.**

(Compl. ¶ 183.) Nowhere did GSK assert or affirm that Zofran® was “safe and effective for treating pregnancy-related nausea.” To the contrary, as previously discussed, Zofran® was not even indicated for the treatment of pregnancy-related nausea.³ Similarly, nowhere did GSK assert or affirm that Zofran® had been “adequately tested and studied in pregnant women.” Again, to the contrary, the label expressly states that Zofran® had *not* been tested in pregnant

³ An “indication” refers to the FDA-approved use of the drug.

women. Lastly, nowhere did GSK assert or affirm that Zofran® “did not increase the risk of bearing children with birth defects.” It merely relayed information obtained from animal toxicology studies. It made no promise whatsoever about the safety or efficacy of Zofran® for use by pregnant women. Accordingly, no express warranty was made, and Count 7 must be dismissed.

Plaintiff’s claim in Count 8 for breach of the implied warranty of fitness for a particular purpose must also fail. An implied warranty for a particular purpose is created where “the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller’s skill or judgment to select or furnish suitable goods.” TEX. BUS. & COM. CODE ANN. § 2.315. While the Complaint recites portions of the applicable statute, Plaintiff does not allege any facts that establish that GSK had any information about how Plaintiff’s physician (i.e. the “buyer”) intended to use Zofran® for treating Plaintiff’s condition. Accordingly, Plaintiff cannot state a claim for breach of implied warranty for fitness for a particular purpose, therefore, that claim must be dismissed.

C. Plaintiff’s Fraud Claims Fail to Meet the Requisite Pleading Standard and Lack the Essential Elements of the Claims

Plaintiff’s claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation do not meet the standards required by Federal Rule of Civil Procedure 8(a) and 9(b) and must be dismissed. Not only has Plaintiff failed to plead her fraud-based claims with the requisite specificity, but she has also failed to state facts demonstrating the required elements to support her claims. For these reasons, her Fourth, Fifth, and Sixth Causes of Action should be dismissed.

Under Rule 9(b), claims of fraud must be pleaded with “particularity.” Rule 9(b)’s heightened pleading standard is only satisfied if the plaintiff supplies “the particulars of time,

place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby, otherwise referred to as the who, what, when, where, and how of the alleged fraud.” *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 384 (5th Cir. 2003) (internal citations and quotation marks omitted). Rule 9(b) is “premised on the goals of weeding out unmeritorious claims and eliminating fishing expedition . . . achieving these goals requires not only providing notice to defendants, but also ensuring that the Court knows what specific conduct is being criticized.” *Ind. Bell Tel. Co. v. Lovelady*, 2006 WL 485305, at *1 & n. 10 (W.D. Tex. 2006) (citing C. Wright & A. Miller, 5A Federal Practice & Procedure § 1296 (2005)).

Here, Plaintiff claims that GSK made four false representations regarding Zofran®, *see supra*, at 8; (Compl. ¶¶ 252, 274), but wholly fails to identify **who, when, where, or in what manner** the alleged misrepresentations occurred. Not only does the Complaint lack detail as to the alleged misrepresentations, it contradicts her assertions. Plaintiff claims that GSK falsely represented that Zofran® was safe and effective for treating pregnancy-related nausea and that Zofran® had been adequately tested and studied in pregnant women (Compl. ¶¶ 252, 274), but the FDA-approved package insert for Zofran® stated, “There are, however, no adequate and well-controlled studies in pregnant women.” (Compl. ¶ 183.) Plaintiff provides no factual basis for her fraud claims.

Plaintiff supports her claim only through general allegations about GSK’s representations through its marketing. But Plaintiff does not identify with particularity to whom, when, or how these representations were made even though a plaintiff “must allege specific facts supporting an inference of fraud.” *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 339 (5th Cir. 2008). The Fifth Circuit has held that it “interprets Rule 9(b) strictly” and, in order to avoid dismissal, a

plaintiff must “specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent.” *Id.* Plaintiff has alleged none of these, yet claims the unspecified representations were “material, false and misleading.” (Compl. ¶ 253.) This is simply not enough to satisfy Rule 9(b). *See Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1019 (5th Cir. 1996) (“[R]ote conclusory allegations that the defendants ‘knowingly did this’ or ‘recklessly did that’ fail to meet the heightened pleading requirements of Rule 9(b).”).

Plaintiff’s fraud-based claims must also be dismissed because she has failed to allege the required elements. To sustain a fraud claim, a plaintiff must plead with particularity “(1) that a material representation was made; (2) that it was false; (3) that when the speaker made it he knew it was false or made it recklessly without any knowledge of the truth and as a positive assertion; (4) that he made it with the intention that it should be acted upon by the party; (5) that the party acted in reliance upon it; [and] (6) that [the party] thereby suffered injury.” *Stone v. Lawyers Title Ins. Corp.*, 554 S.W.2d 183, 185 (Tex. 1977). Here, the only conduct Plaintiff identifies with any degree of specificity is irrelevant to her alleged injury and cannot possibly form the basis for fraud or misrepresentation.

Plaintiff identifies a 1999 FDA letter to support her allegations of fraudulent conduct, (Compl. ¶¶ 199-203), but fails to disclose the fact that the 1999 FDA letter dealt exclusively with promotional material relating to the use of Zofran® for post-operative and chemotherapy-induced nausea and vomiting. The 1999 FDA letter is not relevant to Plaintiff’s alleged use of Zofran® for pregnancy-induced nausea. Plaintiff has not and cannot reasonably allege that her physicians relied on the contents of the 1999 FDA letter and that such content caused her claimed damages.

Likewise, Plaintiff cites GSK's settlement with the Department of Justice in 2012 as a basis for her fraud claims. (Compl. ¶¶ 89, 93.) The settlement, however, related to conduct that allegedly occurred between 2002 and 2004. On its face, this allegation is irrelevant to Plaintiff's fraud claims, which are premised on representations made during Plaintiff's pregnancy with B.C.W. in 2014. (Compl. ¶¶ 134, 145.) Nor has Plaintiff alleged any facts showing a nexus between her physician's treatment decisions and the conduct that allegedly occurred a decade prior to her pregnancy. Accordingly, without more, Plaintiff cannot plausibly plead that her physicians relied on the conduct at issue in the Department of Justice settlement, and that it caused Plaintiff's claimed damages. In any event, the allegations contained in the settlement agreement are not conclusive of GSK's conduct related to Zofran® because there were no findings that GSK illegally marketed Zofran®, and GSK never admitted to any wrongdoing with respect to Zofran®. (See <http://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-ex-b.pdf>.)

Furthermore, Plaintiff has not pleaded facts sufficient to establish reliance. More specifically, Plaintiff neither identifies her prescribing physician nor provides a *single fact* about the content and circumstances of the misrepresentation that Plaintiff alleges induced her physician into prescribing Zofran®. Instead, Plaintiff merely alleges the legal conclusion that "[i]n reliance upon said representations, Plaintiff's prescriber was induced to prescribe Zofran to her," without any factual support. (Compl. ¶ 257.) This is precisely the kind of conclusory allegation that the Supreme Court has condemned for purposes of Rule 8(a) and therefore must be disregarded. See *Twombly*, 550 U.S. at 555; see also *Iqbal*, 556 U.S. at 679 (conclusory allegations without supporting facts have no probative value). Plaintiff's fraudulent concealment and negligent misrepresentation claims suffer from the same defect. See *Frith v. Guardian Life*

Ins. Co. of America., 9 F. Supp. 2d 734, 742 (S.D. Tex. 1998) (Claims alleging “fraudulent concealment and negligent misrepresentation are subject to the requirements of Rule 9(b).”); *see also Lone Star Ladies Inv. Club v. Schlotzsky’s Inc.*, 238 F.3d 363, 368 (5th Cir. 2001) (“Rule 9(b) applies by its plain language to all averments of fraud, whether they are part of a claim of fraud or not”). For all of these reasons, Plaintiff’s Fourth, Fifth, and Sixth Causes of Action should be dismissed.

D. Plaintiff’s Loss of Consortium Claim Fails as a Matter of Law

In her Tenth Cause of Action, Plaintiff alleges that she is entitled to recover for loss of her son’s consortium because she has been deprived of his companionship, care, and services. (Compl. ¶¶ 307-308.) However, in *Roberts v. Williams*, 111 S.W.3d 113, 119 (Tex. 2003), the Texas Supreme Court held that loss of consortium claims to parents of a child who suffered non-fatal injuries are expressly prohibited. The court noted that public policy interests compelled its refusal to extend consortium rights to parents. *Id.* at 116-120 (“Because the parent has a less dependent role than that of the child in the relationship, extending consortium rights here could logically lead to the recognition of such rights in other non-dependent relatives or even in close friends, given appropriate facts.”) Because Plaintiff seeks recovery for loss of consortium of a child with non-fatal injuries, her claim is barred in Texas and must be dismissed.

V. CONCLUSION

Plaintiff fails to provide a legal and factual basis for her negligence per se, express warranty, implied warranty of fitness for a particular purpose, and loss of consortium claims. Further, federal pleading standards demand more than the general, conclusory allegations Plaintiff supplies to sustain her fraud-based claims. Accordingly, the Court should grant GSK’s Motion to Dismiss and dismiss Plaintiff’s Second, Fourth, Fifth, Sixth, Seventh, and Tenth

Causes of Action and dismiss Plaintiff's Eighth Cause of Action to the extent it is based on an implied warranty of fitness for a particular purpose.

WHEREFORE, GSK respectfully requests that this Court:

- a. Grant its Motion to Dismiss;
- b. Dismiss with prejudice Plaintiff's Second, Fourth, Fifth, Sixth, Seventh, and Tenth Causes of Action as well as her Eighth Cause of Action insofar as it is based upon a breach of the implied warranty of fitness for a particular purpose; and
- c. Grant such further relief as this Court deems just and appropriate.

REQUEST FOR ORAL HEARING

GSK hereby requests oral argument on all matters raised in its Motion to Dismiss and supporting Memorandum of Law as well as all matters raised in any opposition thereto submitted by Plaintiff.

Date: May 18, 2015

Respectfully submitted,

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**COUNSEL FOR DEFENDANT
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3) this 18th day of May 2015.

/s/ Hunter K. Ahern

Hunter K. Ahern